



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[EPA-HQ-OPPT-2005-0033; FRL-9369-1]

RIN 2070-AD16

Revocation of TSCA Section 4 Testing Requirements for One High Production

Volume Chemical Substance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule implements EPA's decision to revoke certain testing requirements promulgated under the Toxic Substance Control Act (TSCA) for the High Production Volume (HPV) chemical substance, benzenesulfonic acid, [[4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]- (CAS No. 1324-76-1), also known as C.I. Pigment Blue 61. After publication in the **Federal Register** of a final rule requiring testing for C.I. Pigment Blue 61, EPA received adequate, existing studies which eliminated the need for testing.

DATES: This final rule is effective *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2005-0033, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30

a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

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For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

This action is directed to the public in general and may be of particular interest to those persons who manufacture (defined by statute to include import), process, or export the chemical substance identified in this document. Because other persons may also be interested, the Agency has not attempted to describe all the specific persons that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

A. What Action is the Agency Taking?

In this document, EPA is amending the TSCA section 4(a) chemical testing requirements for one HPV chemical substance included in 40 CFR 799.5085. Specifically, the amendment revokes some of the testing requirements for C.I. Pigment Blue 61. EPA bases its decision on information (discussed in Unit III.) received since publication of the final rule (Ref. 1) that established testing requirements for this chemical substance.

In the **Federal Register** issue of March 16, 2012 (Ref. 2), EPA issued a direct final rule revoking some or all of the testing requirements for 10 chemical substances, including C.I. Pigment Blue 61. EPA received an adverse comment pertaining to a statement in the preamble of the direct final rule that certain full studies for C.I. Pigment Blue 61 had been claimed as Confidential Business Information (CBI) and were, therefore, not available to the public, although robust summaries were available in the docket. The Environmental Defense Fund (EDF) objected to EPA's placing the robust summaries in the docket rather than applying the disclosure requirements of TSCA section 14(b) to the full health and safety studies. Consequently, in accordance with the procedures described in the March 16, 2012 **Federal Register** document (Ref. 2), EPA withdrew the revocation of certain testing requirements for C.I. Pigment Blue 61 in a separate final rule document published in the **Federal Register** issue of May 14, 2012 (Ref. 3), and also published a proposed rule document in the same **Federal Register** issue (Ref. 4) asking for comment. EPA is now issuing the final rule based on the May 14, 2012 **Federal Register** proposed rule document (Ref. 4).

B. What is the Agency's Authority for Taking this Action?

Section 4(a) of TSCA authorizes EPA to require testing if certain findings are made. The TSCA section 4(a) findings include:

1. The chemical substance was produced in substantial quantities.
2. There are insufficient data upon which the effects of manufacture, distribution, processing, use, or disposal of a chemical substance on health or the environment can reasonably be determined or predicted.
3. Testing of the chemical substance with respect to such effects is necessary to develop such data. (See TSCA section 4(a)(1)(B)(i), (ii), and (iii); see also Ref. 1).

EPA amends the testing requirements for C.I. Pigment Blue 61 because some of the findings that EPA made under the criteria listed in this unit for this chemical substance are no longer supported.

III. Amendment to Chemical Testing Requirements

On July 17, 2006, the Color Pigments Manufacturers Association (CPMA) submitted a test plan for C.I. Pigment Blue 61. CPMA also submitted robust summaries of existing data which CPMA asked EPA to accept as satisfying some of the Agency's data needs for C.I. Pigment Blue 61. Some of the existing data described in the summaries addressed C.I. Pigment Blue 56, a close analog of C.I. Pigment Blue 61, which CPMA requested EPA to accept as satisfying the Agency's data needs for C.I. Pigment Blue 61, arguing that there was a sufficiently close structure-activity relationship (SAR) between the two chemical substances to justify that request (Refs. 5 and 6). CPMA also asked EPA to accept results for water solubility and octanol/water partition coefficient that were obtained by using an alternative method, due to the extremely low predicted solubility of C.I. Pigment Blue 61, instead of the methods specified by the test

rule (Ref. 5). Finally, CPMA asked EPA to accept that determining a melting point for C.I. Pigment Blue 61 was not relevant because the pigment thermally decomposes before it melts (Ref. 5).

EPA reviewed the submitted information on physical/chemical properties and decided that melting point, boiling point, and vapor pressure determinations were not relevant because C.I. Pigment Blue 61 decomposes before it melts and the decomposition temperature had been reported (Ref. 7). EPA accepted the submitted data on water solubility as satisfying the Agency's data needs for that endpoint, but did not accept the calculated value submitted to satisfy the testing requirement for octanol/water partition coefficient (Ref. 7). EPA believes the calculated value would, most likely, underestimate the measured value (Ref. 7) required to be determined by the test rule.

EPA reviewed CPMA's SAR argument concerning C.I. Pigment Blue 61 and C.I. Pigment Blue 56 and agreed that C.I. Pigment Blue 56 is an acceptable surrogate for C.I. Pigment Blue 61, thereby allowing adequate data on C.I. Pigment Blue 56 to satisfy data needs for C.I. Pigment Blue 61 (Ref. 8). As a result, a biodegradation study of C.I. Pigment Blue 56, found adequate by an EPA review, satisfies the need for biodegradation data on C.I. Pigment Blue 61 (Ref. 8). Likewise, a fish acute toxicity study and a chromosomal damage test of C.I. Pigment Blue 56, which EPA reviewed and found adequate, will satisfy the data need for those endpoints (Ref. 9) for C.I. Pigment Blue 61. EPA's review of the existing data on C.I. Pigment Blue 61 found the study on mammalian acute toxicity and the bacterial reverse mutation assay to be adequate to satisfy the data needs for those endpoints (Ref. 9). The existing study on repeated-dose toxicity, however, did not satisfy the test requirement for that endpoint (Ref. 9).

Therefore, EPA is revoking the testing requirements for melting point, boiling point, vapor pressure, water solubility, biodegradation, fish acute toxicity, mammalian acute toxicity, bacterial reverse mutation, and chromosomal damage for C.I. Pigment Blue 61 by removing those requirements from those listed for that chemical substance in Table 2 in 40 CFR 799.5085(j). In order to clarify that test requirements for acute toxicity to *Daphnia* (an aquatic invertebrate) and toxicity to algae has not been satisfied by existing studies, and that the fish acute toxicity test requirement has been satisfied, the test symbol C2 replaces C1 for C.I. Pigment Blue 61 in Table 2 in 40 CFR 799.5085(j). The testing requirements for C.I. Pigment Blue 61 that are not revoked include tests for octanol/water partition coefficient, acute toxicity to *Daphnia*, toxicity to algae, and combined 28-day repeated-dose toxicity with a reproduction/developmental toxicity screen (studies responding to those test requirements were conducted and submitted pursuant to the test rule and found by EPA to be adequate (Refs. 10-18)).

IV. Public Comment

Only one comment was received, from EDF, on the May 14, 2012 **Federal Register** proposed rule document (Ref. 4). The EDF comment indicated support for the May 14, 2012 **Federal Register** proposed rule document (Ref. 4) that revoked some of the testing requirements for C.I. Pigment Blue 61. The EDF acknowledged steps were taken to address the concerns that motivated the previous filing of an adverse comment. Namely, the submitter of the C.I. Pigment Blue 61 studies had withdrawn the CBI claim on the studies and the studies were made available to the public. The full studies and EDF's comment are included in the docket for the May 14, 2012 **Federal Register** proposed rule document (Ref. 4).

V. Economic Analysis

In the economic impact analysis for the final rule (Ref. 1) establishing testing requirements for C.I. Pigment Blue 61 and 16 other chemical substances, the Agency estimated the total testing cost to industry to be \$4.03 million for all 17 chemical substances included in that final rule, with an average of approximately \$237,000 per chemical substance (Ref. 19). This total included an additional 25% in administrative costs. An amendment to the final rule revoking testing requirements for coke-oven light oil (coal) reduced the total cost to industry to an estimated \$3.7 million for the remaining 16 chemical substances, with an average compliance cost of approximately \$232,000 per chemical substance. This final rule, combined with the direct final rule revoking all or some of the test rule requirements for 9 other chemical substances (see Ref. 1), would have the effect of further reducing the total testing cost by an estimated \$1.5 million (approximately 41%) (Ref. 20). In addition, the 25% administrative costs would be eliminated for these tests. The reduced total cost for the remaining 12 chemicals is estimated to be \$2.2 million (i.e., \$3.7 million minus \$1.5 million), with an average compliance cost per chemical substance of approximately \$184,000 (Ref. 20).

VI. Export Notification

Persons who export or intend to export C.I. Pigment Blue 61 are and will remain subject to TSCA section 12(b) export notification requirements (See 40 CFR part 707, subpart D).

VII. References

As indicated under **ADDRESSES**, a docket has been established for this final rule under docket ID number EPA-HQ-OPPT-2005-0033. The following is a listing of the

documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Testing of Certain High Production Volume Chemicals; Final Rule. **Federal Register** (71 FR 13708, March 16, 2006) (FRL-7335-2). Document ID number EPA-HQ-OPPT-2005-0033-0001.

2. EPA. Revocation of TSCA Section 4 Testing Requirements Certain High Production Volume Chemical Substances; Direct Final Rule. **Federal Register** (77 FR 15609, March 16 2012) (FRL-9335-6). Document ID number EPA-HQ-OPPT-2005-0033-0402.

3. EPA. Withdrawal of Revocation of TSCA Section 4 Testing Requirements for One High Production Volume Chemical Substance; Final Rule. **Federal Register** (77 FR 28281, May 14, 2012) (FRL-9350-2). Document ID number EPA-HQ-OPPT-2005-0033-0414.

4. EPA. Revocation of TSCA Section 4 Testing Requirements for One High Production Volume Chemical Substance; Proposed Rule. **Federal Register** (77 FR 28340, May 14, 2012) (FRL-9350-1). Document EPA-HQ-OPPT-2005-0033-0415.

5. CPMA. Letter to EPA from J. Lawrence Robinson concerning existing data and test plan. July 17, 2006. Document ID number EPA-HQ-OPPT-2005-0033-0185.

6. CPMA. Letter to EPA from J. Lawrence Robinson concerning existing data and test plan. May 9, 2007. Document ID EPA-HQ-OPPT-2005-0033-0246.

7. EPA. Memorandum from Diana Darling, Industrial Chemistry Branch (ICB), Economics, Exposure, and Technology Division (EETD), OPPT, to Greg Schweer, Chemical Information and Testing Branch (CITB), Chemical Control Division (CCD), OPPT. Testing requirements and existing data for physical/chemical properties of the HPV test rule chemical, C.I. Pigment Blue 61 (CAS No. 1324-76-1). May 17, 2007. Document ID number EPA-HQ-OPPT-2005-0033-0280.

8. EPA. Memorandum from Bob Boethling, Exposure Assessment Branch (EAB), OPPT, to Greg Schweer, CITB, CCD, OPPT. Review of SAR argument and a biodegradation test concerning an HPV test rule chemical, C.I. Pigment Blue 61 (CAS No. 1324-76-1). May 15, 2007. Document ID number EPA-HQ-OPPT-2005-0033-0279.

9. EPA. Email and attached review from David Brooks, Risk Assessment Division (RAD), OPPT, to Greg Schweer and Catherine Roman, CITB, CCD, OPPT. Review of C.I. Pigment Blue (CAS No. 1324-76-1). August 22, 2007. Document ID number EPA-HQ-OPPT-2005-0033-0286.

10. CPMA. Robust summaries submitted for C.I. Pigment Blue 61 on octanol/water partition coefficient, acute toxicity to *Daphnia*, toxicity to algae, and combined 28-day repeated-dose toxicity with a reproduction/developmental toxicity screen. Submitted on November 14, 2008. Document ID number EPA-HQ-OPPT-2005-0033-0318.

11. CPMA. Octanol/Water Partition Coefficient Test study with C.I. Pigment Blue 61. Submitted on April 13, 2012. Document ID number EPA-HQ-OPPT-2005-0033-0440.

12. CPMA. Acute Toxicity Study in the *Daphnia Magna* with C.I. Pigment Blue 61. Submitted on April 13, 2012. Document ID number EPA-HQ-OPPT-2005-0033-0443.

13. CPMA. Fresh Water Algal Growth Inhibition Test with C.I. Pigment Blue 61 study. Submitted on April 13, 2012. Document ID number EPA-HQ-OPPT-2005-0033-0442.

14. CPMA. A Combined 28-Day Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test Study of C.I. Pigment Blue 61 of Rats by Oral Gavage. Submitted on April 13, 2012. Document ID number EPA-HQ-OPPT-2005-0033-0445.

15. EPA. Memorandum and attached review from Tracy Williamson, ICB, EETD, OPPT, to Jim Willis, CITB, CCD, OPPT. Review of Determination of Log Kow for C.I. Pigment Blue 61. Submitted January 20, 2010. Document ID number EPA-HQ-OPPT-0033-0404.

16. EPA. Email and attached review from Ryan Wallace, EAD, OPPT, to Jeff Santacroce, RDMB, IMD, OPPT; Scott Sherlock, EAD, OPPT; and Catherine Roman, CITB, CCD, OPPT. Review of acute toxicity to *Daphnia* of C.I. Pigment Blue 61(CAS No. 1324-76-1). Submitted June 14, 2012. Document ID number EPA-HQ-OPPT-2005-0033-0450.

17. EPA. Email and attached review from Ryan Wallace, EAD, OPPT, to Jeff Santacroce, RDMB, IMD, OPPT; Scott Sherlock, EAD, OPPT; and Catherine Roman, CITB, CCD, OPPT. Review of toxicity to algae of C.I. Pigment Blue 61 (CAS No. 1324-76-1). Submitted July 11, 2012. Document ID number EPA-HQ-OPPT-2005-0033-0453.

18. EPA. Email and attached review from Ryan Wallace, EAD, OPPT, to Jeff Santacroce, RDMB, IMD, OPPT; Scott Sherlock, EAD, OPPT; and Catherine Roman, CITB, CCD, OPPT. Review of repeat-dose toxicity of C.I. Pigment Blue 61 (CAS No. 1324-76-1). Submitted June 14, 2012. Document ID number EPA-HQ-OPPT-2005-0033-0448.

19. EPA. Economic Analysis for the Final Section 4 Test Rule for High Production Volume Chemicals. Prepared by Economic Policy and Analysis Branch (EPAB), EETD, OPPT. October 28, 2005. Document ID number EPA-HQ-OPPT-2005-0033-0131.

20. EPA. Email from Stephanie Suazo to Catherine Roman. RE: “Revised Economic Analysis for Revocation of Testing Requirements” with attached economic analysis. December 14, 2009. Document ID number EPA-HQ-OPPT-2005-0033-0350.

VIII. Statutory and Executive Order Reviews

This final rule only eliminates existing requirements; it does not otherwise impose any new or revised requirements. As such, this action is not subject to review by the Office of Management and Budget (OMB) as a significant regulatory action under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Nor does it impose or change any information collection burden that

requires additional review by OMB under the provisions of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*).

Because this final rule eliminates existing requirements without imposing any new or revised requirements, the Agency certifies pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), that this action will not have a significant economic impact on a substantial number of small entities.

For the same reasons, it is not subject to the requirements of sections 202 and 205 of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531-1538), and does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in UMRA sections 203 and 204. This final rule does not have tribal implications, as specified in Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), or federalism implications as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

Since this action is not economically significant under Executive Order 12866, it is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), and Executive Order 13211, entitled “Actions concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001).

This action does not involve technical standards; thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

The final rule does not involve special consideration of environmental justice related issues as specified in Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

IX. Congressional Review Act (CRA)

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 799

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: May 6, 2013.

James Jones,
Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is amended as follows:

PART 799--[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. In § 799.5085, revise CAS No. “1324-76-1” in Table 2 of paragraph (j) to read as follows:

§ 799.5085 Chemical testing requirements for first group of high production volume chemicals (HPV1).

* * * * *

(j) * * *

TABLE 2--CHEMICAL SUBSTANCES AND TESTING REQUIREMENTS

CAS No.	Chemical name	Class	Required tests (See table 3 of this section)
* *	* * *	*	*
1324-76-1	Benzenesulfonic acid, [[4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]-	2	A4, C2, F1
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